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# Western Europe: Trends in Biotechnology Commercialization

An Intelligence Assessment

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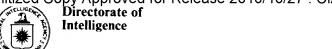
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# Western Europe: Trends in Biotechnology Commercialization

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An Intelligence Assessment

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| Sanitized Copy Appr   | oved for Release 2010/10/27 : CIA-RDP86R00995R000501060001-6   | 2 |
|---|--|---|
|   | Western Europe: Trends in Biotechnology Commercialization  | 2 |
| Key Judgments Information available as of 1 January 1984 was used in this report. | Although Western Europe currently lags the United States and Japan in biotechnology applications, we believe that recent governmental and industrial programs to promote biotechnology will enable Western Europe to become a strong worldwide competitor in health care and agricultural markets within six to eight years. West European countries having the strongest competitive positions are West Germany, the United Kingdom, Sweden, Switzerland, and France. We believe West European companies will develop significant strengths in marketing products to Third World countries. | 2 |
|   | Although many West European firms are pursuing wide-ranging biotechnology interests, we expect competition mainly from large multinational companies in markets in which they have been traditionally strong. These markets include the four top areas for biotechnology applications: pharmaceuticals, agricultural products, large-scale process technology, and energy-related applications.  | 2 |
|   | Forecasts of annual worldwide markets for biotechnology-related products by the year 2000 range from \$15 billion to over \$100 billion in total product sales. This market projection is of the same magnitude as the current world semiconductor market, which is approximately \$25 billion. The estimate of the 1983 worldwide biotechnology market is about \$500 million. Better market predictions are not yet possible, because the critical technical, economic, and political factors affecting future markets are not yet well understood or defined.                             | 2 |
|   | At present the West European countries generally have some top-quality basic research foundations and some industries and engineering institutes with strengths in selected areas of application. Nevertheless, biotechnology developments in Western Europe have been hampered by several problems, including:  • Shortage of qualified personnel to conduct basic and applied research, development, and engineering, caused in part by emigration of scientists and engineers.  |   |
|   | <ul> <li>Difficult transitions from the laboratory to the marketplace.</li> <li>Relatively few firms engaged in innovative research.</li> <li>Lack of cooperation within the European Community.</li> </ul>  | 2 |

Both government and industry are working to overcome these deficiencies, in particular, their support for applied biotechnology research has increased significantly in the past three years. Efforts to promote biotechnology in Western Europe include:

- Public funding that is probably equivalent to Japanese public expenditures and that is intended to help stem emigration of scientists as well as encourage support for commercial developments.
- Financial incentives for small applied research firms.
- Innovative cooperative ventures by industry/government/university in establishing technology parks and centers for applications development, and in investing funds.
- Programs to develop trained manpower.
- International development agreements.

Unlike most US Government programs supporting basic research in biotechnology, these biotechnology-related government programs in Western Europe support product-oriented R&D and are directed toward developing international competitiveness.

Various development agreements have contributed to the international flow of industrial proprietary information that could affect US sales. This flow of information and technology is, and probably will continue to be, a net loss to the United States. However, we believe US technology can be enhanced through selective international cooperation and exchanges that exploit West European strengths.

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#### **Contents**

|  | Pag |
|--|-----|
| Key Judgments  | iii |
| Introduction   | 1   |
| Current Status   | 3   |
| Highlights of Government Programs and Legal and Safety Factors Affecting Biotechnology | 6   |
| Details of National Programs   | 8   |
| Belgium  | 8   |
| Denmark  | 8   |
| Finland  | 9   |
| France   | 9   |
| Italy  | 9   |
| Netherlands  | 10  |
| Spain  | 10  |
| Sweden   | 10  |
| Switzerland  | 11  |
| United Kingdom   | 11  |
| West Germany   | 11  |
|  |     |
| Outlook  | 13  |

25X1

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Tables

| 1. | Some Products for Manufacture by Recombinant DNA Technologies   | 2 |
|----|---|---|
| 2. | Areas of Biotechnology Strengths in Western Europe  | 4 |
| 3. | Known Expenditures of the EEC and of West European Government Organizations for Biotechnology R&D, 1983 | 7 |

|                      | Range of West European Commercial Product Interests in<br>Biotechnology | 5 |
|----------------------|---|---|
| Tales and the second | Examples of National Efforts To Increase University/                    | 6 |
|                      | Private-Sector Cooperation  |   |

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|        |  |

Western Europe: Trends in Biotechnology Commercialization

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#### Introduction

Biotechnology encompasses the newly developing techniques of genetic engineering (recombinant DNA and cell fusion) and biochemical engineering (fermentation and large-scale cell culture). Its application has the potential to increase industrial productivity greatly and to create new products and processes across such diverse industries as pharmaceuticals, agriculture, process chemicals, energy, intelligent biosensors, and integrated microelectronics. Biotechnology applications are expected to result in products with the following advantages:

- · Lower cost.
- Higher purity.
- Larger quantities.
- Decreased pollution.
- Lower energy consumption.
- Unlimited supply.

Additionally, among other driving forces for interest in and support of biotechnology programs is the potential for developing new products, increasing market shares of products, increasing competitiveness, decreasing dependence on foreign raw materials and energy, establishing agricultural self-sufficiency, and attaining future economic security.

Successful commercialization of biotechnology is not guaranteed. In addition to legal, political, and resource issues, many questions remain about the technical and economic feasibility of commercial applications. For example, successful commercialization of biotechnology depends on the efficient and stable functioning of "engineered" micro-organisms, the production of functional products, as well as the development of cost-effective fermentation technologies and the development of product purification or isolation technologies.

Despite the uncertainties of commercialization, many West European corporations have singled out biotechnology as having the highest growth potential for the future and are investing resources now so they will be able to exploit biotechnology developments competitively in the world markets. Similarly, many West European governments have programs to encourage domestic biotechnology commercialization. Table 1 illustrates the broad range of potential products that could be marketed within the next decade.

West European industry and government experts generally expect wide-scale commercialization of biotechnologies over the next five to 15 years. They expect the pharmaceutical/health-care industry to be the first to manufacture products using these technologies. Human insulin and a veterinary vaccine produced by bacteria, engineered by recombinant DNA techniques have already been marketed in the United States and Western Europe. Biotechnological processes for producing chemicals or raw material feedstocks are expected to be developed next (within five to 10 years), followed by certain other agricultural and energy-related advances

Market researchers forecast a \$7.3 billion West European market for biotechnology-related pharmaceuticals by 1990. Forecasts of future worldwide markets range from \$15 billion to over \$100 billion in total product sales by the year 2000. The projected markets for biotechnology-related products represent four to five times the current world semiconductor market, which is approximately \$25 billion. Current estimates of worldwide biotechnology markets are about \$500 million. Better market predictions are not yet possible, because the critical technical, economic, and political factors affecting future markets are not yet well understood or defined.

This paper assesses the extent to which the national programs are likely to increase the productivity and international competitiveness of West European corporations and the extent to which they will thereby affect future worldwide US commercial competitiveness in the multibillion-dollar biotechnology markets.

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Table 1 Some Products for Manufacture by Recombinant DNA Technologies

| Products                      | Potential Uses/Developments  | Products                 | Potential Uses/Developments                            |
|-------------------------------|--|--------------------------|--|
| Agricultural                  | X. *   | Antibiotics              | Infectious disease treatment                           |
| Plant cultivation             | Nitrogen fixation capability   | Vaccines                 | Immunization for disease                               |
|                               | Tolerance for high-salt mediums  |                          | prevention   |
|                               | Tolerance for low-moisture mediums   | Hepatitis A and B Rabies | 4 114  |
|                               | Resistance to diseases   | Influenza                |  |
|                               | Resistance to pests  | Malaria                  |  |
|                               | Increased nutritional quality  | Diphtheria               |  |
| Food-processing agents        | Enzymes  | Polio                    |  |
|                               | Flavorings   | Chemical                 |  |
|                               | Additives  | Commodity chemicals      | Intermediates and bulk chemicals                       |
| Animal husbandry              | Vaccines   | Amino acids              |  |
|                               | Growth hormones  | Acetic acids             | ***************************************                |
| Biological                    |  | Acetone                  |  |
| Biological response modifiers |  | Acrylic acid             |  |
| Hormones                      |  | Adipic acid              |  |
| Insulin                       | Treatment of diabetes  | Citric acid              |  |
| Human growth                  | Treatment of dwarfism and accel-   | Ethanol                  |  |
| hormone                       | eration of wound healing   | Ethylene glycol          |  |
| B-endorphins                  | Treatment of pain  | Ethylene oxide           |  |
| Thymosin alpha-1              | Immune system stimulant  | Glycerol                 |  |
| Erythropoietin                | Stimulation of red blood cell production   | Methanol                 |  |
| Secretin                      | Treatment of digestive problems  | Propylene oxide          |  |
| Somatostatin                  | Treatment of pituitary disease   | Salicylic acid           |  |
| Interferons                   | Treatment of viral diseases and  | Industrial enzymes       |  |
| interterons                   | cancer   | Oxidases                 | Production of glycols                                  |
| Biologicals                   |  | Amylases                 | Production of sugars                                   |
| Albumin                       | Blood expander   | Lignases                 | Production of phenols from wood cellulose for plastics |
| Enzymes<br>Urokinase          | Dissolving blood slots   | Cellulases               | Production of fermentable sugars                       |
| 11 00 1110                    | Dissolving blood clots   |                          | from wood cellulose                                    |
| Clotting factors              | Treatment of hemophilia  | Fibers and plastics      | Production of textiles and plastics                    |
| Bradykinin<br>Glucosidase     | Treatment of high blood pressure  Enzyme replacement therapy (that is, Gauche's Disease) | Cellulosics              |  |

| Table 1 (continued)                    |                             |
|--|-----------------------------|
|  |                             |
|  |                             |
| Products                               | Potential Uses/Developments |
| Chemical (continued)                   |                             |
| Silk                                   |                             |
| Polyhydroxybutyrate                    |                             |
| Pullulans                              |                             |
| Mineral concentrating organisms        | Concentration of metals     |
| Uranium                                |                             |
| Gold                                   |                             |
| Copper                                 |                             |
| Iron                                   |                             |
| Other metals                           |                             |
| Chemicals that organisms can degrade   | Pollution control systems   |
| 2,4-D/2,4,5-T                          |                             |
| 2,4,5-Trichlorophenoxya-<br>cetic acid |                             |
| Polychlorinated biphenyls              |                             |
| Petroleum                              |                             |
| Mercury                                |                             |
| Agent orange (2,4,5-<br>T/2,4-D)       |                             |
| Pesticides and phenoxy herbicides      |                             |
| Specialty chemicals                    |                             |
| Oils                                   |                             |
| Lubricants                             |                             |
| Surfactants                            | St. At                      |
| Energy related                         |                             |
| Ethanol                                | Gasohol, fuel               |
| Hydrogen                               | Fuel                        |
| Methanol                               | Fuel                        |
| Methane                                | Fuel                        |

#### **Current Status**

Generally, West European countries have strong basic research foundations. Although they are about two years behind the United States and Japan in developing biotechnology applications, selected strengths exist (see table 2). For example, Sweden and West Germany are second to Japan and probably equal to the United States in fermentation technology. Switzerland and Sweden are the West European leaders in large-scale process technologies include bioreactor fermentation, isolation, purification and separation technologies, and enable the scaleup of production processes from laboratory to commercial scales. West Germany also has significant capabilities in this field.

Specific products under development or corporate strategies are usually proprietary to the corporation. Most of our information, therefore, is derived from open sources. These sources indicate that West European commercial interests in biotechnology research and development involve a broad range of industrial sectors, products, and new manufacturing processes. West European countries are emphasizing the pharmaceutical and health care, chemical, and agricultural areas in which they are competitive with conventionally manufactured products. The inset shows examples of West European corporate interests and illustrates the broad spectrum of products being selected for commercialization.

West European countries having the strongest competitive positions are West Germany, the United Kingdom, Sweden, Switzerland, and France. Denmark and the Netherlands are competitive in selected markets. All of these countries have strong international corporations in specific markets. We expect increasing competition from West European large international corporations. National government programs are increasing and probably will be effective in overcoming deficiencies within six to eight years.

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# Table 2 Areas of Biotechnology Strengths in Western Europe

|                | Basic Research   | Developmental R&D                           |
|----------------|--|---|
| Belgium        | Molecular biology  |   |
| Denmark        | Enzymology   | Industrial enzymes                          |
| Finland        |  | Agriculture and cellulose utilization       |
| Italy          |  |   |
| Netherlands    |  | Pharmaceuticals and agriculture             |
| Spain          |  |   |
| Sweden         | Agriculture and biomolecular research and bioengineering | Large-scale fermentation technology         |
| Switzerland    |  | Large-scale fermentation technology         |
| United Kingdom | Agriculture and biology                                  | Agriculture, pharmaceuticals, and chemicals |
| West Germany   | Agriculture and biochemical engineering                  | Pharmaceutical and fermentation technology  |
| 5              | č.   |   |

Biotechnology applications development has been slow in Western Europe because of the following factors:

- Lack of qualified scientists and engineers. Because biotechnology is a relatively new field, the number of experienced personnel is limited. The European educational system has not met industry needs, and this problem is exacerbated by a talent drain. The United Kingdom and West Germany are concerned with the emigration of their top talent, especially to the United States. Recent estimates in open literature indicate that of the 7,000 Ph.D. biotechnologists worldwide, 4,000 work in the United States. Only 1,000 work in Western Europe, and 80 percent of these work in West Germany, Switzerland, France, and the United Kingdom. Western Europe is attempting to increase this number and entice scientists now abroad to return home.
- Not enough firms developing innovative technologies. Unlike the United States, Europe has more large corporations than small specialty research firms funded by venture capital. This is a disadvantage because smaller firms are more flexible and can more easily focus resources on an innovative concept. Of an estimated 175 corporations engaged

in advanced biotechnology research and development in Western Europe, less than 20 are innovative specialty firms; some of these, such as Biogen (Switzerland), Transgene (France), and CellTech (UK), have excellent reputations.

- Lack of venture capital for high-risk investments.

  Much of Western Europe's industry has been slow to capitalize on opportunities related to genetic engineering and other advanced technologies. A significant number of West European investors have favored funding US companies, thereby showing a lack of confidence in their national firms to earn profits.
- Inadequate industry/university cooperation. Biotechnology efforts are hindered by a delay in transferring accomplishments in the laboratory to the marketplace. More industry/university cooperation is needed to facilitate this transition. The inset lists some examples of efforts to develop increased industry/university cooperation.

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#### Range of West European Commercial Product Interests in Biotechnology

| Country/<br>Corporation                         | Commercial Product Interests  | Country/<br>Corporation     | Commercial Product Interests  |
|---|---|-----------------------------|---|
| Denmark<br>Novo Industri,<br>AS Danske Suk-     | Insulin and industrial enzymes agriculture, plant genetics, and                             | Switzerland<br>Biogen, NV   | Interferon, vaccines, and bioprocesses  |
| kerfabrikker,<br>AS                             | plant tissue culture  | Hoffmann-<br>LaRoche        | Pharmaceuticals and interferon  |
| France<br>Transgene Elf                         | Interferon, vaccines, pharmaceu-  | Sandoz                      | Pharmaceuticals and agricultur-<br>al crop improvements                         |
| Aquitaine                                       | ticals, and industrial process applications   | United Kingdom<br>ICI, Ltd. | Single-cell protein, biopolymers,   |
| Sanofi Rhone-<br>Poulenc                        | Pharmaceuticals, human growth hormone amino acids, and fer-                                 |                             | chemicals, and fermentation technology  |
|   | mentation technology  | Agritech, Ltd.              | Agricultural crop improvements and large-scale food production                  |
| Netherlands<br>Gist-Brocades,<br>NV<br>Akzo, NV | Enzymes, fermentation, and im-<br>mobilized cell technology<br>Pharmaceuticals and vaccines | Celltech, Ltd.              | technology Health-care diagnostics and industrial-scale process technology      |
| 71,720, 717                                     | 1 mar maceumeurs and vaccines   | West Germany                |   |
| Sweden<br>Fortia/                               | Agricultural crop improvements,   | Hoechst, AG                 | Insulin, pharmaceuticals, agro-<br>chemicals and agricultural crop              |
| Pharmacia                                       | reagents, large-scale processes<br>and equipment, and<br>pharmaceuticals                    | Schering, AG                | improvements  Pharmaceuticals, large-scale process, and fermentation technology |
| Sorigona, AB                                    | Amino acids and fermentation technology   | Bayer, AG                   | Health-care diagnostics and pharmaceuticals                                     |
| Kabi Vitrum,<br>AB                              | Human growth hormone, blood<br>hemophiliac factor VIII, and<br>pharmaceuticals              | Degussa, AG                 | Amino acids, large-scale production technology, and aspartame (sweetener)       |
| AC Biotechnics,<br>AB                           | Large-scale processes for production of chemicals, energy substrates, and pharmaceuticals   |                             |   |

### Examples of National Efforts To Increase University/Private-Sector Cooperation

Denmark

Public and private sources have coinvested in Genesit, Ltd., a venture organization established to bridge research institutes and industry.

France

Government and industry sources are cofunding technology transfer centers at universities in Paris for a microbial data bank: Avignon, for microbial engineering; Toulouse, for fermentation and biochemical engineering; and Compeigne, for process engineering.

Sweden

Government and industry sources are cofunding technology parks (at Lund) and research laboratories at Uppsala University and Stockholm University.

United Kingdom Government and industry sources are cofunding technology parks (at Leichester and Cambridge), investing in venture companies (Celltech Ltd. and Agritech Ltd.), and university consortiums.

West Germany Government and industry sources are cofunding institutes and universities in Heidelberg, Cologne, Berlin, and Munich.

## Highlights of Government Programs and Legal and Safety Factors Affecting Biotechnology

The main contribution of government programs supporting biotechnology is to channel resources toward a specific goal. Once a country's strategy for biotechnology development is determined, funding and manpower priorities are established and policies are coordinated. This focus probably will consolidate the national effort in specific areas and expedite results.

For example, various programs involving increased funding and the creation of high-quality research centers have been developed to encourage scientists to remain at home and to return from abroad. We believe the programs will provide the necessary incentives to reduce Western Europe's shortage of bioscientists.

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Government programs will supply a substantial amount of biotechnology funding. Previous analysis and reports of the European Economic Community (EEC) indicate that West European public expenditures probably are equivalent to Japanese and US public expenditures. West European public funds, however, are directed toward R&D that is more applications oriented than that in the United States (see table 3).

We believe that government programs in Western Europe also will be instrumental in encouraging cooperation among industries and universities. Closer associations will smooth the transition from laboratory to commercial applications, help in training scientists and engineers, and establish the confidence that is the basis for investment capital and entrepreneurship. Governments are supporting both universities and industries by sponsoring technology centers, university programs, tax-incentive plans, and innovative research firms.

The European Economic Community (EEC) supports programs for research in biotechnology. The EEC has currently allocated \$30 million for a 1982-84 biomolecular engineering program focusing first on agricultural applications and development of fermentation technology, and second on applications in pharmaceuticals, chemicals, and enzyme engineering. Research programs are aimed primarily at improving the competitiveness of West European industry and agriculture. The European Molecular Biology Organization (EMBO) in Heidelberg was set up by the EEC in 1971 to undertake research that no one country could reasonably afford.

EMBO has developed a novel genetic engineering technology that could have commercial significance.

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Table 3
Known Expenditures of the EEC and of West European
Government Organizations for Biotechnology R&D, 1983

Million US \$

|                | EEC<br>Estimate a | Organizations  | CIA<br>Estimate |
|----------------|-------------------|--|-----------------|
| Total          | 124.0             |  | 179.7           |
| Belgium        | 6.0               | National Industrial Research Association             | NA_             |
|                |                   | Walloon Regional Government                          | 19.3            |
|                |                   | Flanders Regional Government                         | 14.6            |
| Denmark        | 2.5               | National Industrial Research Association             | NA              |
| Finland        |                   | National Fund for Research and Development (SITRA)   | NA              |
| France         | 26.4              | Ministry of Research and Industry                    | 48.0            |
|                |                   | National Center for Scientific Research              | 8.5             |
|                |                   | National Institute for Agricultural Research         | 4.2             |
|                |                   | National Agency for Commercialization of Research    | 7.0             |
|                |                   | National Institute for Health and Medical Research   | 4.3             |
| Italy          | 11.0              | Ministry of Science and Research                     | 9.0             |
| •              |                   | National Research Council                            | 4.0             |
| Netherlands    | 8.5               | Biotechnology Commission for Industrial Application  | 4.3             |
| Spain          |                   | Unknown  | 0.65            |
| Sweden         |                   | Federal Board for Technical Research and Development | 6.1             |
| Switzerland    |                   | National Science Foundation                          | NA              |
| United Kingdom | 39.0              | Department of Industry                               | 10.1            |
|                |                   | Department of Agriculture                            | NA              |
|                |                   | Medical Research Council                             | NA              |
|                |                   | Science, Engineering, and Research Council           | 4.5             |
|                |                   | Agricultural Research Council                        | NA              |
|                |                   | British Technology Group                             | 18.0            |
| West Germany   | 30.6              | Ministry of Research and Technology                  | 23.3            |

<sup>&</sup>lt;sup>a</sup> The European Economic Community estimates were prepared using the same definition of biotechnology and shows a similarity in magnitude with financial data available from our sources. Accurate estimates of expenditures are difficult to obtain mainly because of a lack of a universally accepted definition of biotechnology.

We believe that the effect of these EEC programs will be hindered because community cooperation in this field will be difficult and several countries that are the leaders in the biotechnology industry—notably Sweden and Switzerland—are not EEC members. Development of community cooperation in the field therefore will be a difficult task. We believe that EEC programs will have little impact on cooperative commercial development of biotechnology.

The Organization for Economic Cooperation Development (OECD) in Western Europe has organized an ad hoc group to study safety and regulations in biotechnology. The group will review country positions, identify criteria that have been or are being adopted for monitoring or authorizing the use of genetically engineered organisms, and explore ways of monitoring

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their use in the future. The group is to report its findings and progress to the Committee for Scientific and Technological Policy of OECD before June 1985. This is seen as an effort to formulate common West European policies.

Industrial-supported programs include numerous international licensing agreements and joint venture arrangements. These arrangements are intended to make up for a lack of basic research and industrial technology or to secure marketing positions. Also, our data indicate that two international companies conducted cooperative research and development to secure a strong competitive position for both companies. The two companies will exchange complementary technology as well as divide markets geographically. These measures will allow the two companies to compete effectively internationally and secure a position in the future for other companies.

In addition to government and university support, we expect biotechnology commercialization to be facilitated by changes in legal and safety requirements, as well as by technology transfer. We expect West European countries to modify existing laws and legal procedures affecting biotechnology. Some countries have begun the process of modernizing patent laws. Problems related to patent law presently include lack of clear definitions, lack of international uniformity and continuity (including such factors as requirements for microbial culture banking), and enforcement issues. Also, because of the long leadtimes required for biotechnology commercialization, patent periods probably will be extended to encourage R&D for commercial applications. Instances of countries giving their own firms or international firms making significant domestic investments preferential treatment in regulatory and legal process probably will increase to provide advantages for domestic interests.

As experience in industrial-scale production and confidence in the safety of the technology are gained, we expect to see a relaxation in regulatory guidelines for commercial production developments. West European countries are watching the United States and will probably take cues from US activities and experiences. West European regulatory guidelines for recombinant DNA R&D, which are similar to guidelines promulgated by the US National Institutes of

Health, are voluntary for industry. US industrial-scale production of a product above 10 liters requires approval by the appropriate government agency. Direct human applications of genetic engineering techniques have not provided much controversy or debate in Western Europe because they seem remote and hence are not an issue. As long as regulations continue to become less restrictive, we believe that the West Europeans will not change their guidelines significantly from those of the United States in the near future.

#### **Details of National Programs**

#### **Belgium**

The Belgium National Industrial Research Association coordinates R&D projects at various research institutes. Priority areas are genetic engineering, chemical production, fermentation technology, plant improvements, monoclonal antibodies, and immobilized enzyme technology for production. The recent reform of the Belgium national government has encouraged regional governments to develop active industrial policies for renewal of industry through the development of new technologies. The Walloon regional government is investing \$19 million for 1983-84 on biotechnology R&D, with an emphasis on fermentation. The Flemish regional government is investing \$15 million.

#### Denmark

Public and private sources in Denmark spent \$74 million for biotechnology R&D in 1983. The Government of Denmark is planning to increase investments and to increase funding for education in biotechnology. It is looking for measures that will increase cooperation between government and industry to expedite technology transfer from the laboratory to commercial development. These plans aim at stimulating Danish industry to apply biotechnology competitively and to increase export markets. The Danes see an increased demand for quality researchers, and they are recruiting international talent as well as proposing creative arrangements to allow personnel to work in both university and industry environments.

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Danish industries will have a significant impact on world markets for pharmaceuticals and industrial enzymes. Novo industri, AS and Nordisk Insulin are two of the world's largest companies producing insulin and/or industrial enzymes. Ninety-eight percent of Novo's markets are foreign; its products are distributed in as many as 120 countries.

#### Finland

The Finnish National Fund for Research and Development (SITRA) is financing innovative basic research in genetic engineering. SITRA and several firms formed Genesit to support research in recombinant DNA and the industrial applications of biotechnology. Genesit discovered secretion vectors in *Bacillus subtilis* during a three-year research project and has applied for a patent. Genesit will act as a bridge between research institutes and its corporate shareholders—Alko Oy, Farmos Group, Metsaliiton Teollisuus, Nestle Petroleum, Suomen sokeri Oy, and Valio. We have no information on levels of funding.

#### France

France has named biotechnology as one of its six high-priority technologies of the future. The French expect a \$66 billion biotechnology world market by then and believe that only a few large groups will be competitive. To achieve future economic objectives, science and technology improvements are essential. The government intends to decrease the deficiencies in basic research and industrial development. Specific goals for the biotechnology industry are to capture 10 percent of the world market by 1992, to decrease the need for foreign imports of oil, and to increase the use of biomass as feedstocks for chemicals.

The Ministry of Research and Industry makes policy and sets funding levels for the developing French biotechnology industry. The ministry is coordinating government/university/industry cooperation and is providing financial assistance to firms. A three-year mobilization program that began in 1981 was formulated to help France catch up with Japan, the United Kingdom, and the United States. The objectives of the program are to decrease dependence on foreign technology, patents, and licensing; increase the number of qualified trained researchers; increase and coordinate the links between government, universities,

and industry; and increase industrial incentives. In addition, loans administered by an industrial modernization fund will be extended at low interest rates and lease credits will be available to induce enterprises to acquire capital equipment. Additional measures to promote biotechnology and other high-technology areas are:

- Establishment of four technology transfer centers.
- Two-year leave of absence for employees wishing to start their own enterprises.
- Tax exemptions for industrial enterprises created after 1983 that eliminate direct taxes during their first three years of operation.
- Options by local communities to grant newly created enterprises exemptions from business and real estate taxes.
- Establishment of a national export school to provide a specialization in the export-import field.

The Ministry for Research and Industry budgeted \$105 million for biotechnology promotion and reportedly will increase its 1984 budget to \$124 million. French industry, indifferent in the past, is now showing interest. Targeted areas for industrial application of biotechnology are microbiology (requires importing of foreign talent), fermentation technology (France is weaker than West Germany, the United Kingdom, and Japan as well as the United States), enzyme engineering, immunology, and agriculture. A center for plant genetic engineering will be created to aid and coordinate all the projects in this field.

Contracts with the EEC, Japan, Canada, Norway, Sweden, and Austria will be sought. International agreements, particularly with Japan, are seen as methods for strengthening the weaker sectors. Government research institutions and industries will set up projects for industrial application development. France will concentrate on those areas where considerable work has been done and markets are already established.

#### Italy

Although the government spent only \$750,000 on biotechnology R&D in 1980, the Ministry for Scientific Research is proposing a combined government

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and industry support program that would allocate \$91 million over five years to support R&D. The allocation includes \$45 million from the government, \$31 million from industry, and \$8 million from the National Research Council. (Salaries of researchers are not included in these funding levels.) Industry interest and investment in biotechnology R&D is recent and is increasing.

#### **Netherlands**

The Committee on Biotechnology, a Cabinet-level organization with members from the Ministry of Economic Affairs and the Ministry of Education and Science, will spend \$30 million over the next seven years for industrial innovation in biotechnology. Most of this allocation is for agriculture, food processing, chemicals, pharmaceuticals, and waste treatment; education programs to increase the number of quality researchers have also been recommended.

Industry will have access to government-sponsored R&D if they provide 50 percent of funding. In addition, the Ministry of Economic Affairs is offering firms the following lucrative incentives for developing products and processes in the Netherlands: 70-percent loan of development costs; interest at 5 percent; repayment of interest and principal required only upon successful sale of the products; up to 15 years to repay; and industry retention of rights and controls.

#### Spain

Spain will target biotechnology for industrial applications development. The Spanish Government sees biotechnology as an aid to the lagging drug industry, which has shrunk with the closing of about 30 firms. Strong overseas competition, punitive price controls, and overly strict regulatory procedures are all in part to blame. The government has moved to restore balance to the industry by financing six projects on drug-related biotechnology through the Industrial and Technological Research Council. It also invested \$650,000 for a 51-percent share in a joint industrial venture with Sobrina Laboratories to establish Immunologia y Genetics Aplicado, SA.

#### Sweden

The Swedish 1983/84 biotechnology budget is small. Only S&T programs have escaped government cuts.

The Council for Planning and Coordination of Research (FRN) considers biotechnology to be of importance to Swedish industry. Since April 1983 FRN has been working on a study plan to map out and coordinate various programs in an attempt to formulate a national policy. The Ministry of Industry's National Board for Technical Development gives biotechnology a high priority and will receive an increase in its current budget. Biological processes have only been exploited to a limited extent by industry, primarily in the pharmaceutical and diagnostics field. Planned applications are in forestry and agriculture and chemical industry including biological measurement and control techniques, separation technology, and genetic engineering. The Council for Forestry and Agricultural Research, which is subordinate to the Ministry of Agriculture, is responsible for long-term basic research including biotechnology, soil ecology, and fishery biology. It received a 21.8percent increase over last year's budget to intensify efforts in priority areas such as food and soil ecology.

The Swedish National Board for Technical Development administers government funding in biotechnology. In 1981-82 the government spent \$1.9 million and private industry was estimated to have spent \$3 million on biotechnology R&D. The government level for biotechnology support was \$5.3 million for 1982-83. Support is expected to increase to \$6.1 million for 1983. The government also is funding the construction of a biology laboratory at the University of Stockholm at the \$25 million level that is to be completed in 1984. This effort is to help increase industrial international competitiveness and stimulate industry and academic cooperation.

Industrial interest in biotechnology is increasing, and contacts with the university are developing. The Swedish industry is positioning itself securely. The Swedes will compete internationally very well, especially as suppliers of materials and equipment for biotechnology development. Agriculture and pharmaceuticals also will be emphasized. There is a Foundation for Biotechnical Research in Scandinavia that raises money for R&D, disseminates information, and helps direct research to finished products.

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#### **Switzerland**

The Swiss Government involvement in genetic engineering and biotechnology is gaining momentum. Both federal and cantonal governments are sponsoring R&D in biotechnology. Five cantonal universities have programs in biotechnology-related basic sciences that are funded by the cantonal government. The federal government also supports specific projects at the cantonal universities, but no funding estimates are available. In 1981 federal funding established the Institute of Biotechnology in Zurich. A second unit to study waste treatment and environmental engineering problems was built at the Ecole Polytechnique Federale de Lausanne. The government provides major funding for molecular biology centers at the universities of Zurich and Geneva and at the University of Basel's Biocenter. Federal funding supports the Federal Institute of Technology (ETH) in Zurich, one of Europe's leading research centers. The ETH is developing bioreactors for plant and animal growth and also separation equipment.

The Swiss National Foundation is the main conduit for government funds, but it funds only half of the cost of submitted projects. The other half comes from industries, which do most of their own development. Biotechnologists complain that Swiss industry prefers investment abroad.

#### **United Kingdom**

Government support for biotechnology R&D has been increasing in the United Kingdom since 1981, especially for product and process development. In April 1982 an interdepartmental committee was created to coordinate government, industry, and university efforts in the development of industrial applications. Membership includes the Medical Research Council, Agricultural Research Council (ARC), Science and Engineering Research Council, the Public Health Laboratory Service, and the Center for Applied Microbiology and Research. The Department of Industry is providing \$32 million over three years for support of biotechnology industrial applications. It will invest in pilot development projects enabling the private sector to develop products and processes. The department wants to attract overseas companies to establish branches in the United Kingdom. So far, 2,500 companies have approached the department for money. The British Technology Group (BTG) provides

equity and loan finance for innovative ventures. The British Government and BTG commitments equal \$90 million. BTG is funding 14 biotechnology projects and corporate ventures including Celltech, Ltd. and Agritech, Ltd.

#### West Germany

In addition to a general emphasis on basic and generic applied research in biotechnology, West Germany is supporting biotechnology development in pharmaceuticals and plant agriculture (that is, developing crops resistant to disease and environmental stresses). Continued support should result in a firmly competitive position for West Germany in these fields. West Germany's Ministry for Research and Technology (BMFT) spent \$23.3 million in 1983 and will spend \$26-48 million in 1984 to support industrial and basic biotechnology research projects. The ministry is prepared to increase its biotechnology support if enough qualified bioscientists could be found to staff projects.

BMFT's goals are to improve the general conditions for industrial research and development and to promote university and industry cooperation. Funds go directly to universities, industrial laboratories, the German Research Foundation, Institute for Biotechnology, and other institutions. The BMFT will provide 50 percent of the funding for two or more companies to engage in joint R&D ventures. This is to make up for the lack of small specialty genetic engineering companies and the lack of entrepreneurship. The BMFT is funding demonstration projects for largescale production of single-cell protein and advanced fermentation bioreactors. Increased promotion measures and tax benefits are being used as industry incentives, as well as for foreign travel for biotechnology scientists.

The universities are offering more courses in microbiology, genetics, and biochemistry that are oriented toward preparing students for employment in industry and are establishing new biotechnology laboratories and expanding present facilities. Additionally, large companies support research at West German universities—Bayer, AG at Cologne Max Planck, BASF at

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By 1990 we expect the main competition for the biotechnology-related market to be among the West European multinational firms and their US and Japanese counterparts. Although West European firms will not be at a significant disadvantage in employing biotechnology developments, they will be slower in commercializing them and in competing with US firms on a wide scale. However, they may be highly competitive in selected markets where traditional strengths exist (for example, Novo Industries, AS in insulin production and Hoechst, AG in pharmaceutical production). Almost all West European countries will keep pace in research methodologies and will add significantly to the world's knowledge of biotechnology.

#### Outlook

Although only two to three years old, national programs and individual corporate efforts to commercialize biotechnology already have helped West European scientists, engineers, and businessmen understand the importance of being on the leading edge of biotechnology developments. Selected achievements testify to the competence of West European scientists, but wide-scale engineering developments are still lacking as is the case for the United States and Japan. We believe that these programs and efforts are laying the groundwork for engineering developments and will accelerate Western Europe's competition position.

The extent to which Western Europe can become competitive in commercial and industrial developments in biotechnology will depend heavily on the success of government and industry programs. We judge that they will be successful and that West European multinational firms will be competitive in biotechnology markets within six to eight years.

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